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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,822	11/28/2000	Matthew D. Linnik	252312007400	7723

25226 7590 12/03/2002

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EXAMINER	
QIAN, CELINE X	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 12/03/2002

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/724,822	Applicant(s) LINNIK ET AL.	
	Examiner Celine X Qian	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 September 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-12,14-20,33 and 35-92* is/are pending in the application.

4a) Of the above claim(s) *21-32 and 40-64* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-12,14-20,33-39 and 65-92* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 November 2000* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *7,11,16* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 1, 3-12, 14-33, 35-92 are pending in the application.

Election/Restrictions

Applicant's election without traverse of Group I in Paper No. 15 is acknowledged.

Accordingly, claims 21-32, 40-64 are withdrawn from consideration for being directed to non elected subject matter. Claims 1, 3-12, 14-20, 33, 35-39 and 65-92 are currently under examination.

Drawings

The drawings are objected to because of the informalities as indicated by Draftsperson on PTO form 948 (see attached form). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance. Any response to this office action which does not response to the above objections will be considered non-responsive.

Claim Objections

Claims 3 and 14 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The parent claims recite "wherein the dsDNA epitopes are polynucleotides. Claims 3 and 14 recite "wherein the polynucleotides are double stranded DNA." Therefore, claims 3 and 14 do not further limit parent claims 1 and 12.

Claim Rejections - 35 USC § 112

Claims 1, 3, 33, 35-39, 65-72 and 90-92 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The written description requirement is set forth by 35 U.S.C. 112, first paragraph which states that the: "*specification* shall contain a written description of the invention..." The written description requirement has been well established and characterized in the case law. A specification must convey to one of skill in the art that "as of the filing date sought, [the inventor] was in possession of the invention." See *Vas Cath v. Mahurkar* 935 F.2d 1555, 1560 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). Applicant may show that he is in "possession" of the invention claimed by describing the invention with all of its claimed limitations "by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention." See *Lockwood v. American Airlines Inc.* 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

In analyzing whether the written description requirement is met, it is first determined whether the whether a representative number of species have been described by their complete structure. Next, it is determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics. The claims recite a conjugate "comprising a non-immunogenic valency platform molecule and **two or more molecules** comprising double stranded DNA epitopes..." The specification only discloses a conjugate

comprising two or more double stranded DNA attach to the non-immnunogenic valency platform molecule. There are no other molecules attach to the platform molecule disclosed throughout the specification. The specification also fails to describe the characteristic or structure these molecules must share. Therefore, the invention is not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors had possession of the claimed invention at the time the application was filed.

Claims 1, 3, 4, 8, 9, 10, 12, 14, 15, 19 and 65-89 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The nature of the invention is a method of treating systemic lupus erythematosus (SLE) in an individual comprising administering a conjugate comprising double stranded DNA (dsDNA) attached to a non-immunogenic valency platform molecule, wherein the treatment is based on high affinity of antibodies (from SLE patients) to dsDNA. The specification discloses that patients with high initial affinity of the antibodies to the conjugate such as LJP394 show more favorable responses to the treatment. The specification further discloses that the patients with initial Kd <0.8 respond to the treatment more efficiently than patients with Kd>0.8.

The art is silent on said method of treating SLE by measuring initial antibody-dsDNA affinity. The teaching of the specification indicates specifically that such method is efficient in patients with Kd<0.8. However, the breath of the claims is broad. The claim recites such a method with unknown Kd or other equivalent affinity value (such as claim 1) or with Kd at 1.0. Since the prior art is silent on such method of treating SLE, one skilled in the art would have to

rely on the guidance provided by the specification to practice said method. The specification teaches that patients with Kd>0.8 do not respond to LPJ394 effectively. Therefore, one skilled art would have to engage in undue experimentation to practice the method as claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-12, 14-20, 33, 35-39 and 65-92 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 1, 3, 10, 12, 14, 33, 35-39, 76-82 and 90-92, the recitation "wherein the dsDNA epitopes are polynucleotides" renders the claims indefinite because it appears to be redundant to recite that dsDNAs are polynucleotides. It is well known that dsDNA consists polynucleotide. It is unclear what other molecules dsDNA would consist.

Regarding claims 4-9, 11, 15-20, 33-39, 73-75 and 83-92, the recitation of "about 1.0 mg" or "about 0.8"...etc renders the claims indefinite because the value of Kd is unclear. For example, is 0.9 "about 1.0" or "about 0.8?"

Regarding claims 33, 35-39 and 90-92, there are two (a)s and two (b)s recited in the claims. It is recommended to use different numbering systems to indicate different steps or components.

Claims 1, 3, 10, 12, 14, 33, 35-39, 65-72, 76-82 and 90-92 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: 1) How to

determine whether a patient will receive or continue to receive the treatment based on affinity. In other words, what is the parameter to for making such decision. 2) How to determine whether the patients are treated.

Claims 4-9, 11, 74, 75, 83-89 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: How to determine whether the patients are treated.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 10, 12, 14, 66-68, 69-72 and 77-82 are rejected under 35 U.S.C. 102(b) as being anticipated by Jones et al. (1995, J. Med. Chem. Vol 38, pages 2138-2144).

The claims are drawn to a method of treating systemic lupus erythematosus (SLE) in and individual comprising administering to the individual a conjugate comprising a non-immunogenic valency platform and two or more dsDNA epitopes, wherein affinity of the dsDNA for the antibody is used as a basis for selecting patients to receive the treatment. The claims are further drawn to said method wherein the dsDNA is $(GT)_{10}$ and the platform molecule is as shown in claim 10.

Jones et al disclose the synthesis of a conjugate LPJ394 comprising a non-immunogenic platform molecule and four dsDNA epitopes (see Figure Scheme 1 and 2, pp2139-2140). Jones

et al. further disclose that this conjugate binds specifically to anti-ds-ON antibodies in serum of mice immunized with anti-KLH antibodies (see page 2141, 2nd col., last paragraph through page 2142, first paragraph). The specificity is determined by Farr assay which indicates the affinity of the antibodies to the conjugate. Jones et al. further disclose that treatment of immunized mice with LJP 394 significantly reduced the number of antibody forming cells in a dose-dependent manner (see page 2141, 2nd col., 3rd paragraph). Lastly, Jones et al. disclose that this conjugate has entered clinical trials for human with SLE. Therefore, Jones et al. disclose the instantly claimed invention. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 703-306-0283. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Celine Qian, Ph.D.
December 2, 2002

PATENT EXAMINER